

REMARKS

Claims 1-42 were examined. Applicant has amended claims 1-2, 30-31 and 38-42. Support for these amendments can be found at least in paragraphs [0112], [0116], [0190] and [0225]. Claims 8-14 and 25 have been cancelled and Claim 43 has been added. No new matter has been introduced. All amendments were made without prejudice or disclaimer. Applicants explicitly reserve the right to pursue any deleted subject matter in one or more continuing applications.

Objections to the Drawings

Applicant has amended the claims to comply with 37 CFR 1.83(a). Applicants submit that at least figures 39-41 support the use of surgical techniques to pre-position tissue at the tissue site.

Rejections under 35 USC §112

Claims 1-39 stand rejected under §112, second paragraph, as being indefinite. In particularly, the examiner states that claims 1, 30 and 39 include improper alternatives not presented in the accepted Markush format; and that claims 1, 30 and 39 contain the trademark/trade name Steri-strip™, which mark should be capitalized.

The examiner also notes that wherever the trademark Steri-strip™ appears in the specification, the mark should be capitalized, and be accompanied by the generic terminology.

Applicant has amended the claims to remove the alternatives at issue and amended the specification to include capitalization of the trademark STERI-STRIPTM and accompanying generic terminology as suggested by the examiner.

Rejections under 35 USC §102

Claims 1-11, 14-24, 26-29, 31-40 and 42 stand rejected under §102(b) as being anticipated by Knowlton (US 6,350,276) in view of Dressel (US 4,985,027).

The Applicant respectfully disagrees. Nevertheless, without acquiescing to the examiners position, Applicant submits herewith further amendment to Claim 1 in order to clarify what the Applicant has always considered to be the invention. Support for these amendments can be found at least in paragraphs [0116] and [0225]. As amended, Claim 1 now reads:

A method of energetically treating a target tissue site, the method comprising:

- pre-positioning tissue at the site of treatment into an aesthetically corrected configuration; wherein pre-positioning of the selected tissues is used to reduce the resting skin tension of the treatment site and create a directed wound healing response so as to create or facilitate the shaping of a thermal lesion;
- delivering energy to the tissue site using an energy delivery device;
- securing tissue in the aesthetically corrected configuration by producing a thermal adhesion or lesion at the tissue site; and
- remodeling at least a portion of tissue at the tissue site.

The '276 patent of Knowlton provides a method and apparatus that delivers a mechanical force and electromagnetic energy to a tissue site to change a skin surface and/or change the contour of a soft tissue structure. The apparatus includes a template with a skin interface surface that is used to conform the tissue using mechanical compression.

As stated in the Declaration of Dr. Knowlton submitted December 15, 2008, based on his factual first hand experience with using the method disclosed in the '276 patent, the '276 method does not adequately secure the repositioned skin in place or sufficiently produce a desired amount of tissue remodeling. Furthermore, the '276 patent does not teach pre-positioning tissue at the site of treatment into an aesthetically corrected configuration; wherein pre-positioning of the selected tissues is used to reduce the resting skin tension of the treatment site and create a directed wound healing response so as to create or facilitate the shaping of a thermal lesion, as claimed in the instant application. In addition, the '276 patent does not disclose securing tissue in the aesthetically corrected configuration by producing a thermal adhesion or lesion at the tissue site.

The Examiner is reminded that the standard for anticipation under 35 U.S.C. §102(b) is strict identity. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Further, the identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Applicants respectfully submit that the '276 patent and the supporting Dressel reference do not teach each and every element of the claims.

The Examiner has asserted that Knowlton ('276) discloses

... a method of energetically treating a target tissue site (col 11-12, thermal), the method comprising: pre-positioning tissue in a[n] aesthetically (background on the invention, such as line 40-42 and inherent positioning of the patient for access) correct configuration (cols 19-20, lines 62-3, contact and pressure are required otherwise there is not current flow) wherein prepositioning of the selected tissues (via inherent surgical positioning to access and work on the cite, disclosed liposuction a pretreatment including positioning, the conforming template which is prepositions prior to energetically treating and the template “can be separate” therefore prepositioned “with the energy delivery device”, col 13, lines 48-50) is used to shape a thermal lesion so as to create or facilitate the creation of a directed wound healing response (i.e. the lesion is formed on moved tissue); ... (page 5 of the instant Office Action).

First, Applicant submits that the Examiner’s breakdown of each element in claim 1 of the instant application and its pairing with disclosures in the ‘276 patent are both erroneous and taken out of context. For example, the examiner asserts, “pre-positioning tissue in a[n] aesthetically (background on the invention, such as line 40-42 and inherent positioning of the patient for access) correct configuration (cols 19-20, lines 62-3, contact and pressure are required otherwise there is not current flow)...”. The Examiner appears to be piecing together different parts of the prior art reference in an attempt to cover the teaching of the instant application. This of course would be considered using hindsight, which is impermissible under the law. Simply identifying the use of individual terms or attempting to fit a random disclosure in the prior art with an element of the instant invention is disingenuous to the intended meaning of the claimed method.

More specifically, the instant method claims pre-positioning tissue at the site of treatment into an aesthetically corrected configuration. The disclosure in the ‘276 patent that “many esthetic procedures involve the reduction of the soft tissue contents with or without a reduction in the skin envelope.” (background, lines 40-42) certainly does not anticipate the instant invention because it is identified separately in the background section and is not combined with other elements in the detailed description of the ‘276 patent that would teach the combined use of all elements of the instantly claimed method. In addition, while reduction of tissue contents may take place prior to “esthetic procedures”, the removal of tissue does not necessarily place the tissue being treated into an aesthetically corrected configuration as required by the instantly claimed method. Moreover, removal of tissue does not teach that pre-positioning of the selected

tissues is used to create a directed wound healing response so as to create or facilitate the shaping of a thermal lesion, as in Claim 1 of the instant application.

With regard to the Examiner's assertion that the disclosure in the '276 patent stating that "contact and pressure are required otherwise there is no current flow" somehow reads on "correct configuration", Applicant submits that this completely misinterprets the obvious meaning of aesthetically corrected configuration as pertaining to the pre-positioning of tissue and not, as the Examiner alleges, the arrangement of contact sensors as disclosed at col. 19-20, lines 62-3 of the '276 patent.

Applicant further submits that Knowlton ('276) does not disclose pre-positioning tissue at the site of treatment into an aesthetically corrected configuration; wherein pre-positioning of the selected tissues is used to reduce the resting skin tension of the treatment site , as currently amended. Prepositioning of the selected tissues via use of a conforming template, as suggested by the Examiner, would not comply with this limitation as it is clear from the disclosure of the '276 patent that such templates are used in conjunction with mechanical compression . Reducing the skin and/or tissue structure tension does not require mechanical compression and is important for providing a more natural realignment of tissue structures and allowing thermal contraction to proceed at lower thermal doses.

With respect to the Examiner's assertion that the inherent positioning of the patient for access amounts to pre-positioning of the tissue, Applicant submits that such a general interpretation does not adequately take into account all the limitations disclosed in claim 1 for the prepositioning of tissue at the treatment site. Further, not only would it not provide enablement for the instantly claimed method, but it would also not necessarily create or facilitate the shaping of a thermal lesion as required by the limitation of claim 1.

With regard to liposuction, the Examiner again appears to be using hindsight to incorporate this element into the disclosed method of Knowlton ('276). Apart from the background, Knowlton ('276) makes no further mention of liposuction in the description of the claimed apparatus or methods of its use. In fact, Knowlton ('276) specifically discloses that an object of the invention is to provide a method and apparatus to tighten skin without major surgical intervention. As such, the Examiner has not demonstrated that the identical invention is shown in as complete detail as is contained in the claim. Nevertheless, even if liposuction was to be used prior to energetically treating a target tissue site, this type of surgical treatment in and of

itself would not necessarily pre-position tissue at the site of treatment into an aesthetically corrected configuration nor facilitate the shaping of a thermal lesion or adhesion.

Applicant further submits that the '276 patent does not disclose securing tissue in the aesthetically corrected configuration by producing a thermal adhesion or lesion at the tissue site. In fact, as stated in the previously submitted Declaration by Dr. Knowlton, the method and apparatus disclosed in US Patent 6,350,276, using a conforming template combined with mechanical compression, does not adequately secure the repositioned skin in place or sufficiently produce a desired amount of tissue remodeling, at least to the extent accomplished by the instant application.

In addition, Applicant submits that the '276 patent does not disclose a method of energetically treating a target tissue site comprising producing a plurality of thermal adhesions at the tissue site, wherein the plurality of adhesions is substantially continuous or uniform in thickness or other dimension, as presented in claims 4-7 and 31-38 of the instant application. The Examiner's asserts that col. 6, lines 5-48, teach discontinuous modes/pattern of application and that lines 22-23, specifically states power is pulsed which is overlapping and a pattern. (Page 6 of the instant Office Action) Applicant submits that the Examiner is again taking material out of context. The section of the '276 patent cited by the Examiner refers to the detailed description of different cooling and heating control algorithms that can be employed in different combinations of continuous and discontinuous modes of application. Lines 20-27 of col 6 read:

Example delivery modes include the continuous application of the cooling means in which the flow rate is varied and application of the power source is pulsed or continuous i.e., the application of power can be applied in a pulsed fashion with continuous cooling in which the flow rate of cooling solution and the rate of RF energy pulsing (at a set power level) is varied as a function of surface monitoring of tissue interface 21.

Contrary the Examiner's assertion, this section of the '276 patent does not teach delivering energy in a selected pattern or grid pattern and producing a plurality of thermal adhesions at the tissue site, wherein the plurality of adhesions is substantially continuous or uniform in thickness or other dimension.

Further, Applicant submits that the '276 patent does not disclose skeletonizing at least a portion of fibrous septae at the tissue site (claim 28). Contrary to the Examiner's assertion that this is an "unintended side effect as discussed in Col 12, lines 34-49" of the '276 patent, the instant application teaches that the fibrous septae receive higher thermal doses due to higher

current densities produced in these skeletonized structures (vs. surrounding tissue) and at the same time become more mechanically and thermally susceptible to thermal tightening due to collagen contraction. The overall effect is enhanced aesthetic contouring. (paragraph [0229])

The Applicant also submits that the '276 patent does not disclose a method of energetically treating a target tissue site using patient feedback to titrate the delivery of energy to the treatment site as in currently amended claim 30.

Finally, Applicant submits that claims 40-42 of the instant application are directed to a method of energetically treating a target tissue site comprising positioning tissue at the tissue site into an aesthetically corrected configuration after the delivery of energy; wherein post-positioning of the selected tissues is used to shape a thermal lesion so as to create or facilitate the creation of a directed wound healing response. Applicant notes that the Examiner failed to note this distinction in the instant Office Action.

Accordingly, withdrawal of the rejection of Claims 1-11, 14-24, 26-29, 31-40 and 42 under 35 U.S.C. §102(b) is respectfully requested.

Rejections under 35 USC §103

Claims 1-42 stand rejected under 35 USC §103(a) as obvious over Knowlton (6,350,276) in view of Dressel (US 4,985,027).

Applicants maintain, for the reasons above and previously made of record in the Response of December 15, 2008 and September 18, 2007, that Knowlton does not disclose each and every limitation of Claims 1, 30 or 39 or those claims dependent thereupon, because Knowlton does not disclose pre-positioning tissue at the site of treatment into an aesthetically corrected configuration; wherein pre-positioning of the selected tissues is used to reduce the resting skin tension of the treatment site and create a directed wound healing response so as to create or facilitate the shaping of a thermal lesion. Nor does the '276 patent teach securing tissue in the aesthetically corrected configuration by producing a thermal adhesion or lesion at the tissue site. Dressel does not cure the deficiencies of Knowlton ('276).

Applicant further points out that Knowlton ('276) does not teach positioning tissue at the tissue site into an aesthetically corrected configuration after the delivery of energy; wherein post-positioning of the selected tissues is used to shape a thermal lesion so as to create or facilitate the creation of a directed wound healing response

Accordingly, since the instant claims are not anticipated nor obvious over Knowlton ('276), Applicants respectfully request withdrawal of the present rejections under 35 U.S.C. §103(a).

CONCLUSION

Applicant believes that the application is in condition for allowance. Should there be any further issues outstanding, the Examiner is invited to contact the undersigned at the number provided below. The Commissioner is authorized to charge Deposit Account **50-4634** referencing Attorney Docket No. **KNW-0018 (123913-183031)** for any payment due in connection with this paper, including petition fees and extension of time fees.

Respectfully submitted,

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